 Protocol #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

 (ACHS Use only)

**DRAFT Category 3: Benign Behavioral Interventions with Adults Application for Exemption Form**

Primary Investigator(s), Department, Email:

1.

2.

3.

Researcher's Status (Check One):

 Undergraduate Student

 Graduate Student

 Faculty

 Other (Explain):

Research assistants (anyone other than PI or Faculty Advisor who will have contact with participants; the reason is that the researcher is therefore responsible to assure that all assistants are briefed on the ethical treatment of participants and the maintenance of confidentiality)

1.

2.

Faculty Advisor (if PI is a student) Department, Email:

1.

2.

Title of Project:

Desired Start Date: \_\_\_\_\_\_\_\_ Upon Approval

 \_\_\_\_\_\_\_\_\_\_ Other: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_

 Please state why, e.g. grant deadline or class deadline so committee can prioritize if needed.

Expected End Date: \_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_

Length of Project:

\*Note: Approval is only good for one (1) calendar year from date of approval. After that year, the researcher must inform the committee if the research is ongoing in writing.

Will this research be submitted to an external agency for funding?

If yes, please name agency: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

A. How will information be collected and recorded? (check all that apply)

 \_\_\_\_Verbal responses

 \_\_\_\_Written responses

 \_\_\_\_ Audio recording

 \_\_\_\_ Audiovisual recording

 \_\_\_\_Other; describe:

B. Will participants be the age of majority (typically 18 years of age or older)?

\_\_\_\_ No

If No, STOP! This is not the correct form. Refer to the ACHS website for additional information.
\_\_\_\_Yes

1. **Study Information.** Please briefly describe the study using the questions below.
	* + 1. Describe the benign behavioral intervention.
			2. How will participants’ identity be protected so that confidentiality will be maintained?

* + - 1. If the research involves deception, the participant must be informed that they will be mislead or unaware of the nature or purposes of the research.

\_\_\_\_This research does not involve deception.

\_\_\_\_This research involves deception.

 Describe how the participant will be fully informed.

* + - 1. Purpose and background of the research

This is a chance for you to give the reviewers a background in the area of interest. Provide enough information in order for the reviewers to understand the purpose of the research.

* 1. Background (what literature exists in this area of interest? What literature exists in this area and how does this project add to our knowledge of the phenomena of interest? Please include basic citations (author and year only) of existing literature. (**NOTE:** This should not be a literature review; instead provide a background for the reviewers who may not be from your discipline to understand the project at hand.)
	2. Define Terms: Because reviewers are not necessarily from the same discipline as the researcher, we need researchers to define terms and concepts for us. For example, what is known by psychology might not be known by communication, e.g. helicopter parents, snowball sampling.
	3. Methods: Explain the methods to be used in gathering the data and recording the data.
	4. Research question and/or hypotheses: Please tell us your research question and any hypotheses you might have.

5. What is the projected date of destruction and method of destruction of consent forms and other documentation?

 6. Additional Information, Clarification, or Comments for the IRB Reviewer:

**INVESTIGATOR’S ASSURANCE STATEMENT**

I have read Muskingum University's policy concerning research involving human subjects and by signing below:

1. I agree to accept responsibility for the ethical conduct of research conducted in this project;
2. I agree to obtain approval from the Animal Care & Human Subject’s committee prior to modifying any of the procedures that might affect an exempt determination;
3. I attest that the information submitted in this application is true to the best of my knowledge.

Principal Investigator(s):

Date

Date

Date

Faculty Review of Student Projects: I have reviewed and approved the procedures to be used in the project described in this application. I agree to meet with the investigator on a regular basis to monitor study progress and ensure that the well-being of subjects is adequately safeguarded, and ethical standards are maintained.

Faculty Advisor(s):

Date

Date

Basic Exempt Criteria *45 CFR 46.101(b)(4)* [eCFR :: 45 CFR 46.104 -- Exempt research.](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.104)

(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § 46.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.